American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

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August 4, 2014

The Honorable Margaret Hamburg, MD
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20933

Dear Commissioner Hamburg:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 62,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, I write to offer comments on the proposed rule to extend the jurisdiction of the Food and Drug Administration (FDA) to all types of tobacco products, published in the *Federal Register* on April 25, 2014. (Docket No. FDA-2014-N-0189).

The vast majority of those who die prematurely from tobacco-related disease began to use tobacco before the age of 18, and for this reason we call tobacco use a "pediatric disease." The goal of reducing the morbidity and mortality related to tobacco use by preventing youth initiation and exposure to secondhand smoke has guided the AAP's decades-long efforts to improve tobacco control in the United States and across the globe. For this reason, the Academy strongly supported the passage of the Family Smoking Prevention and Tobacco Control Act, which was signed into law in 2009. Today, we are delighted to write in strong support of extending the FDA's authority under that law to encompass all tobacco products, including currently unregulated products such as e-cigarettes and cigars, which are both heavily marketed towards and thus increasingly popular among youth.

The AAP has developed comprehensive comments on the proposed rule, which follow this cover letter. The following points summarize the AAP's primary recommendations:

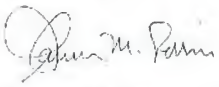
- We strongly support the FDA's proposal to expand its regulatory authority by deeming all types of products "made or derived from tobacco" subject to the Food, Drug and Cosmetic Act, including e-cigarettes, cigars, hookah, and others.
- We strongly oppose the proposed option in the rule that would exclude so-called "premium cigars" from any regulation.
- We support the FDA's proposal to add an addictiveness warning to all tobacco products and support six rotating warnings for cigars.
- We support the FDA's proposal to prohibit the sales of newly deemed products, including e-cigarettes, to those under the age of 18.

- We support the FDA's proposal to prohibit certain vending machine sales of newly deemed products, but encourage the FDA to impose additional sales restrictions including a prohibition on self-service tobacco displays, a minimum pack size (particularly for small cigars), and either enforceable age verification for or a complete prohibition on all Internet sales.
- We encourage the FDA to impose restrictions on the marketing of all tobacco products, including a prohibition on sport/event sponsorships and the use of celebrities and cartoons in advertising. We encourage the FDA to limit child and youth exposure to tobacco advertising on television and other media, including Internet content, to the maximum extent possible, using youth audience, rather than youth-targeted media, as the standard for exposure.
- We encourage the FDA to prohibit the use of any flavors other than tobacco in any tobacco products due to their well-documented appeal to children and youth.
- We implore the FDA to immediately require child-resistant packaging on liquid nicotine containers to prevent the emerging and serious danger to children posed by liquid nicotine poisoning.
- We urge the FDA to include warnings on liquid nicotine products informing parents about the serious risk of child poisoning from these products and the need to keep them out of the reach of children.
- We encourage the FDA to conduct a comprehensive assessment of the child poisoning risks posed by all types of tobacco products and to put in place needed regulations to protect children.
- We encourage the FDA to prohibit cigarette manufacturers from circumventing the existing cigarette flavor ban by mislabeling their cigarettes as cigars.
- We oppose the FDA's proposal to offer newly deemed products a two-year grace period before taking enforcement action against unapproved products. We believe any grace period should be as short as possible, and in no case should be longer than one year, recognizing that the sharp increase in non-smoker use of e-cigarette products requires urgent and timely action.
- We implore the FDA to allow no enforcement grace period whatsoever for manufacturers of liquid nicotine products that fail to sell their products in child-resistant packaging.
- We urge the FDA not to grant a compliance period of any length for products sold in characterizing flavors other than tobacco or any covered tobacco products that use marketing practices known to appeal to children and youth.
- We encourage the FDA to publish a final rule as soon as possible but no later than April 25, 2015. The speed of the development of nicotine dependence in adolescents makes it essential for the FDA to act as quickly as possible.
- If the FDA chooses to address in a separate rulemaking (1) product standards such as a flavor prohibition and child-resistant packaging and (2) restrictions on marketing, we encourage the FDA to publish such final regulations to coincide with the publication of the final deeming rule.
- We encourage the FDA to revise its methodology for determining the costs and benefits of the proposed regulation to not discount the benefits of the proposal due to lost pleasure from decreased tobacco use since the continued use of an addictive product most likely initiated during childhood or youth cannot be considered

rational behavior, initiation by nonsmoking youth results in harmful addiction without any benefit to the nonsmoker, and the vast majority of those under 18 who become addicted generally report wanting to quit but have been unsuccessful in doing so.

We thank you for your dedication to the health and well-being of children. We look forward to continuing to work with you to achieve a tobacco-free future for children.

Sincerely,



James M. Perrin, MD, FAAP
President

JMP/jdb

Importance of FDA Regulation of Tobacco Products

Since the landmark Surgeon General's Report of 1964 that first publicly stated that smoking can cause heart disease, cancer, and other adverse outcomes, the process of placing regulatory safeguards on tobacco products, especially those designed to prevent youth tobacco initiation, has taken slow and deliberate efforts by the public health community to develop. Subsequent to the Surgeon General's Report, volumes of evidence indicating the addictiveness of nicotine and the danger of tobacco products to the public health, including studies performed at the Food and Drug Administration (FDA) in the early 1990s, made the need for regulation of these products at the federal level self-evident.[1]

Tobacco use is a "pediatric epidemic" that begins overwhelmingly before the age of 18, and many youth progress from smoking occasionally to smoking daily, translating into over 1 million new tobacco users every year.[2] Adolescents and young adults, whose brains are still developing, are highly susceptible to influence by peer tobacco use, the use of tobacco in social areas and gatherings, the use of tobacco by individuals in the media, and even the misguided association of tobacco use with weight loss.[3] Each day over 3,200 children smoke their first cigarette and over 2,100 youth who were occasional smokers become daily smokers.[4] In addition to regular smoking, exposure to secondhand smoke can have serious health consequences for children, including middle ear disease, respiratory symptoms and impaired respiratory function, respiratory illness, and increased risk of Sudden Infant Death Syndrome (SIDS).[5] Overall, mortality among individuals who smoke is three times higher than non-smokers, and 1 in 3 youth who become regular smokers will die of a tobacco-related disease.[6,7]

The initial efforts taken by the FDA to regulate tobacco products in 1995 were ended prematurely five years later by the U.S. Supreme Court.[8] The Family Smoking Prevention and Tobacco Control Act, signed into law in 2009, amended the Food, Drug,

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[1] Glynn, T. *The FDA and Tobacco Regulation Three Years Later*. 29 Oct. 2012. http://www.cancer.org/cancer/news/expertvoices/post/2012/10/29/the-fda-and-tobacco-regulation-three-years-later.aspx.

[2] U.S. Department of Health and Human services. Preventing tobacco use among youth and young adults. Centers for Disease Control and Prevention. 2012. http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/exec-summary.pdf.

[3] Ibid.

[4] Smoking and tobacco use. Centers for Disease Control and Prevention. 24 Apr. 2014. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/.

[5] U.S. Department of Health and Human Services. 2014 surgeon general's report: The health consequences of smoking – 50 years of progress. Centers for Disease Control and Prevention. 2014. http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.

[6] Ibid.

[7] Health effects of tobacco. *Partnership for a Tobacco-Free Maine*. 2014. http://www.tobaccofreemaine.org/channels/parents/learn_more_about_health_effects.php.

[8] FDA v. Brown & Williamson Tobacco Corp. 529 U.S. 120. 2000. http://supreme.justia.com/cases/federal/us/529/120/case.html.

and Cosmetic Act to create clear authority for the FDA to regulate tobacco products. The FDA's new authority under this law is crucial as past attempts by "Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health…problems caused by the use of tobacco products."[9] More specifically, the law granted the FDA new and unprecedented authority to protect the public health by "set[ting] national standards controlling the manufacture of tobacco products" and to "impose appropriate regulatory controls on the tobacco industry."[10] While the Tobacco Control Act gave the FDA immediate authority ever cigarettes, smokeless tobacco, and roll-your-own tobacco, Congress left it for the FDA to extend through rulemaking its authority to other previously unregulated types of tobacco products.

There have been numerous public health victories related to tobacco in the 50 years since the publication of the first Surgeon General's Report. These successes have included increasing regulations on the cigarette industry since the 1970s, including a ban on TV and radio advertising for cigarettes,[11] bans on in-flight smoking on domestic airline flights,[12] the passage of the Tobacco Control Act, increased tobacco taxes, and public smoking bans in a majority of states. Despite these successes in tobacco control, there is still a glaring need for FDA regulatory authority over all tobacco products, a crucial step in preventing tobacco products inappropriate for the protection of public health from entering the market. The tobacco industry's ingenuity in designing novel tobacco products that escape current regulation has created a "shifting landscape" of innovation that makes protecting the public health, and especially the health of children, increasingly difficult without regulation that deems all tobacco products under FDA regulatory authority.[13] While combustible tobacco sales have declined over the past decade[14] sales of electronic cigarettes (e-cigarettes) have increased, especially among youth, with the percentage of high school students who had ever tried an e-cigarette doubling from 4.7% to 10% from 2011 to 2012.[15] While youth initiation of e-cigarettes and other alternative tobacco products is increasing, so too are youth rates of cigar use, which are similarly unregulated by the FDA. Further regulation is needed from the FDA to protect the public health and the health of children.

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[9] *Family Smoking Prevention and Tobacco Control Act*. PL 111-31; 123 Stat. 1776. 22 June 2009.
[10] Ibid.
[11] *Smoking and Tobacco Use*. Centers for Disease Control and Prevention. http://www.cdc.gov/Tobacco/.
[12] Ibid.
[13] Cruz, M. and L. Dayton. A New Regulatory Challenge: Youth and Tobacco. *Pediatrics*. 19 Apr. 2010 125(1066). http://pediatrics.aappublications.org/content/125/5/1066.full.pdf+html.
[14] Consumption of Cigarettes and Combustible Tobacco – United States, 2000-2011. Centers for Disease Control and Prevention. *MMWR*. 3 Aug. 2012. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6130a1.htm.
[15] E-cigarette use more than doubles among U.S. middle and high school students from 2011-2012. Centers for Disease Control and Prevention. Press Release. 5 Sept. 2013. http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html.

Currently, proponents of e-cigarettes and other non-combustible tobacco products argue that these products may be used as a safer source of nicotine than combustible tobacco products and may be used to help current smokers quit. Research, however, has yet to prove that e-cigarettes are effective for smoking cessation, let alone that the potential harm reduction benefit of these products outweighs the potential negative consequences, such as increasing youth tobacco initiation. The federal court system has foreclosed the possibility of regulating most e-cigarettes (those not making specific health claims) as drug/device combinations, meaning that the FDA cannot force e-cigarette manufacturers to use drug and device approval pathways at FDA to assure that e-cigarettes are safe and effective through robust clinical data. A U.S. appeals court decided in 2010 that any product containing nicotine derived from tobacco leaf that is not marked with health claims must be regulated as a tobacco product, rather than as a drug or medical device, and as such, there is a great need for FDA regulation of these products under its tobacco authority.[16]

The Tobacco Control Act gave the FDA the authority to ultimately regulate all tobacco products in a science-based manner. We strongly support strong FDA regulation to prevent today's children from becoming tomorrow's tobacco users dying prematurely from tobacco-related disease. The FDA's action to assert jurisdiction over the complete universe of tobacco products is a commendable and landmark moment in the history of tobacco control.

Health Concerns Related to Tobacco Products Not Currently Subject to FDA Regulation

While cigarettes, smokeless tobacco, and roll-your-own tobacco are currently subject to regulation by the FDA, all other tobacco products currently fall outside of the agency's authority. The following sections outline some of the numerous health concerns the AAP has regarding the numerous tobacco products that are currently unregulated by the FDA, including e-cigarettes, cigars, hookah, pipe tobacco, certain dissolvable products, and any other tobacco-derived or nicotine-containing product.

E-Cigarettes

Currently, little is known about the effects of e-cigarette vapor on children. The emissions from e-cigarettes have been publicized as "harmless water vapor," but accumulating evidence demonstrates that the vapor inhaled into the user's lungs does contain numerous known toxins and carcinogens such as formaldehyde and tobacco-specific nitrosamines, albeit at levels markedly lower than those found in traditional cigarettes.[17] In addition, the lack of regulation of these products has resulted in a problematic range of quality control standards for e-cigarettes and the ingredients of the

[16] Sottera, Inc. v. Food & Drug Admin., 627 F.3d 891, 893 (D.C. Cir. 2010).

[17] Goniewicz ML et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tobacco Control.* 2014; 23:133–139.

liquid used in them. Studies by the World Health Organization (WHO) and the FDA have indicated that in addition to propylene glycol, other humectants have been found such as glycerin and diethylene glycol, which "has a history of mass poisonings and death when inadvertently substituted for propylene glycol in consumer products."[18] Because these products are not current regulated, little research has been performed on the effect of these ingredients and other detected substances, including "irritants, solvents, genotoxins, and animal carcinogens," on children and adolescents.[19]

Further, the levels of particulates that are emitted from e-cigarettes are not very different from combusted cigarettes.[20] These particulates could cause respiratory irritation for those nearby. In fact, preliminary animal model data shows damage to growing lungs resulting from second-hand exposure to e-cigarette vapor.[21] The negative health impact of e-cigarettes on children and non-smokers deserves more research. However, until and unless we know that these emissions do not cause harm, particularly to developing lungs, there is an imperative to limit exposure of children and other non-smokers. Swift regulation by the FDA is needed to establish quality control standards for these products and to develop research on the effects of these products on developing children.

Quality standards for e-cigarettes and their ingredients are inconsistent or severely lacking, putting children at risk. Too little research has been performed to establish the presence of toxic ingredients in liquid nicotine, the dose of nicotine delivered to the user, the effects of e-cigarette vapor on lung function, the health effects of e-cigarette vapor as compared with combustible tobacco products, and general safety information for these products.[22] Research, including clinical trials, data collection, and consumer research performed by tobacco product manufacturers and the Department of Health and Human Services (HHS), is necessary to establish whether, and more importantly under what conditions, these novel tobacco products may be beneficial for the public health.

Further, it is unknown if the availability of these products leads to smoking initiation among non-smoking youth, and whether experimentation with these products leads to nicotine addiction. Without such data, we worry that e-cigarettes could lead to a lifetime of nicotine addiction for an adolescent and could serve as a gateway to use of traditional cigarettes or other tobacco products. Use among young people is growing: in just one year, the ever and current use of e-cigarettes doubled among U.S. high school students,

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[18] Cobb NK et al. Novel nicotine delivery systems and public health: The rise of the "e-cigarette." *American Journal of Public Health* 2010; 100: 2340-2342. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2978165/pdf/2340.pdf.

[19] Ibid.

[20] Fuoco FC, Buonanno G, Stabile L, Vigo P. Influential parameters on particle concentration and size distribution in the mainstream of e-cigarettes. *Environ Pollution* 2014;184:523-529.

[21] Testimony of Susanne E. Tanksi, MD, MPH, FAAP. "Aggressive E-Cigarette Marketing and Potential Consequences for Youth." Senate Committee on Commerce, Science, and Transportation. 18 June 2014.

[22] Cobb NK et al. Novel nicotine delivery systems and public health: The rise of the "e-cigarette." *American Journal of Public Health* 2010; 100: 2340-2342.

from 4.7% in 2011 to 10.0% in 2012 (for ever-use). While the rate of having tried e-cigarettes is still far lower than that of cigarettes, as of 2012, approximately 1.78 million U.S. students reported using an e-cigarette.[23] While the overwhelming majority of e-cigarette triers had also smoked cigarettes, some 7.2% of high school ever-users of e-cigarettes had never tried a traditional cigarette.[24] A more recent internet-based study in 2013-2014 found markedly higher rates of ever-use and current-use: 14% of 13-17 year olds had ever used an e-cigarette, and 9% currently used them. Among ever-cigarette users aged 13-17, 32% were current e-cigarette users.[25] Unfortunately, these numbers still may not tell the full story. With the introduction of "e-hookahs" and "vape-pens" to the category, asking only about "e-cigarettes" may significantly underestimate the use of nicotine-containing vapor devices.

The adolescent brain appears uniquely susceptible to nicotine addiction, with symptoms of dependence appearing within days to weeks of intermittent tobacco use and well before the initiation of daily smoking.[26] Nearly all adult smokers initiated smoking before the age of 20, and younger age of tobacco initiation predicts greater levels of dependence and difficulty quitting.[27] Animal studies have demonstrated that nicotine exposure during the adolescent period has long-standing effects on the brain including cell damage that leads to both immediate and persistent behavioral changes.[28] These effects are not seen with nicotine exposure to the adult, supporting the idea that the adolescent is uniquely susceptible to nicotine addiction. The weight of evidence suggests that nicotine exposure modifies the developing adolescent brain and has long-term impacts into adulthood.[29]

There is not a specific threshold of nicotine exposure that predicts addiction, but the source of the nicotine does seem to make a difference. It has been shown that nicotine replacement therapies have low potential for dependence due to how they are absorbed.[30]

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[23] Testimony of Susanne E. Tanksi, MD, MPH, FAAP. "Aggressive E-Cigarette Marketing and Potential Consequences for Youth." Senate Committee on Commerce, Science, and Transportation. 18 June 2014.
[24] Centers for Disease Control and Prevention. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012. *Morbidity and Mortality Weekly Report.* September 6, 2013,62(35);729-730.
[25] American Legacy Foundation. Vaporized: E-Cigarette, Advertising and Youth. Available at http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf 2014. Accessed June 16, 2014.
[26] Difranza JR, et al. Initial symptoms of nicotine dependence in adolescents. *Tobacco Control.* 2000,9:313-319. Difranza JR, et al. Symptoms of Tobacco Dependence After Brief Intermittent Use. *Arch Pediatr Adol Med.* 2007;161(7):704-710.
[27] Chen J. Millar WJ. Age of smoking initiation: implications for quitting. *Health Rep.* 1998 Spring;9(4):39-46.
[28] Slotkin, TA. Nicotine and the adolescent brain: insights from an animal model. *Neurotoxicology and Teratology. 2002,*24: 369-384.
[29] U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014 (Health consequences of nicotine exposure, pages 120-122)
[30] Benowitz NL. Nicotine Safety and Toxicity. New York: Oxford University Press; 1998.

At present, it is not known how amounts and rates of nicotine delivery from e-cigarettes and nicotine-containing vapor devices affects nicotine addiction, nor is it known how many individuals beginning use with e-cigarettes persist with e-cigarettes alone or also initiate combusted tobacco use. Given that these products have only recently begun to be examined, there have not to date been any trajectory studies done with youth or young adult populations. The FDA and the National Institute on Drug Abuse (NIDA) are collaborating on the Population Assessment of Tobacco and Health (PATH) study that will assess these trajectories. However, they are still recruiting the baseline study sample and have no longitudinal data. The present cross-sectional data of adolescents and young adults from other studies suggests that dual use—using both e-cigarettes and combusted products like cigarettes—is the most common status among e-cigarette users. There is concern that e-cigarettes may impede individuals from quitting smoking, by allowing them to maintain their nicotine addiction in places where combusted tobacco has been prohibited. If these individuals would otherwise have quit combusted tobacco completely, the maintenance of use supported by e-cigarettes is of concern.

Anecdotal reports and limited data suggest that e-cigarettes may help smokers quit or reduce smoking. At this time, further research is necessary to determine if—and most importantly, under what conditions—e-cigarettes could play a beneficial role in reducing tobacco-related disease. E-cigarette companies are alluding to numerous potential health benefits from e-cigarettes in their marketing campaigns without appropriate data to support these implications. By comparison, FDA-approved nicotine replacement therapies such as nicotine gum have been carefully evaluated for their safety and efficacy in assisting tobacco cessation in the context of specific, evidence-based instructions for use. In the case of e-cigarettes, there are no instructions on how to use the products to achieve smoking cessation. Additionally, data show that current e-cigarette users include distant-former smokers—smokers who quit more than 5 years ago—suggesting that e-cigarettes could be leading to the re-addiction of former smokers.[31] Given the vast differences in the engineering of e-cigarettes, the doses and chemosensory variations of the e-juice, and the complete lack of quality standards at present, it is extraordinarily difficult to quantify the public health consequences.

E-cigarettes create yet another cause for concern: the re-normalization of smoking. Smoking has become an unpopular behavior among young people, with smokers having to go outside and in many cases off campuses to smoke. As such, smoking is not as often seen as it was 20 years ago. The increase of people smoking e-cigarettes in places where smoking is not currently allowed creates confusion, particularly among children, who often cannot tell the difference between smoking and e-cigarette use. Anecdotally, when I've shown children pictures of people using e-cigarettes, they nearly always report that the person in the picture is smoking. We know that children do what they see, and they

[31] McMillen RC. Trends in electronic cigarette us among US adults: use is increasing in both smokers and non-smokers. Social Climate Survey of Tobacco Control, Mississippi State University. Personal communication.

overestimate the prevalence of behaviors that they see in media, hence it is important that we not allow e-cigarette use to re-normalize the image of a smoker.

E-cigarettes deliver nicotine derived from tobacco. Contrary to some claims, nicotine itself is not a benign substance. Nicotine is a psychoactive drug that is well known for its high level of toxicity and its addictive nature. At low doses it acts as a stimulant, leading to a feeling of pleasure and a reversal of unpleasant withdrawal symptoms. Nicotine affects the reward pathways of the brain, and targets receptors throughout the body allowing the substance to have broad physiological effects. With repeated exposure to nicotine, tolerance to some of the effects of nicotine develops, and leads to needing more nicotine. Insufficient nicotine in someone who is dependent leads to craving and withdrawal symptoms of irritability, anxiety, restlessness, and anhedonia.[32] The basis of nicotine addiction is reinforcement of behavior that restores nicotine and makes the user feel good and avoid withdrawal.[33] Regular users develop habits associated with nicotine use that also become connected with the rewarding feelings of nicotine use, creating cues for use. This is how smokers become cued to want a cigarette after a meal, or with coffee, or in certain locations, for example. Cigarettes are carefully engineered to deliver nicotine quickly and efficiently to the brain to reinforce addiction. The cigarette is the delivery device, but nicotine is the basis of the psychoactive effects.

An overdose of nicotine can cause nausea, vomiting, abdominal pain, headache, dizziness, and seizures. In very high doses nicotine can be lethal. Nicotine, in chemical form, is required to carry a material safety data sheet (MSDS) warning users to handle it with gloves, goggles, mask and protective clothing. The MSDS summarizes the acute potential health effects as follows:

> *Skin: It can cause skin irritation and rash. It may cause dermatitis. It is well absorbed by dermal exposure route. May be fatal if absorbed through skin. Systemic effects similar to that of ingestion can occur from nicotine poisoning.*
>
> *Eyes: It can cause eye irritation. Severe pain, lacrimation, conjunctival reaction, corneal infiltration, partial opacification of cornea.*
>
> *Inhalation: It is well absorbed by inhalation exposure route. Inhalation can produce systemic effects similar to that of ingestion.*
>
> *Ingestion: May be fatal if swallowed. It can cause gastrointestinal tract irritation/disturbances with nausea, vomiting, diarrhea, stomach pain, burning sensation of the mouth, throat, esophagus, and stomach, loss of appetite. Metabolic acidosis and hypokalemia can develop if there is severe diarrhea. It acts on the central nervous system and other parts of the nervous system such as the adrenal medulla, autonomic ganglia, and neuromuscular junctions with initial stimulation followed by depression. Early signs of toxicity from small doses include nausea, vomiting, headache, dizziness, tachycardia, hypertension, tachypnea, hyperpnea, sweating, and salivation. High exposure can cause dizziness, headache, tremors, anxiety, restlessness, seizures, hypotonia,*

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[32] Testimony of Susanne E. Tanksi, MD, MPH, FAAP. "Aggressive E-Cigarette Marketing and Potential Consequences for Youth." Senate Committee on Commerce, Science, and Transportation. 18 June 2014.
[33] Benowitz NL. Nicotine Addiction. *New England Journal of Medicine*. 2010, 362:2295-230.

decreased deep tendon reflexes progressing to paralysis, fasciculations, convulsions, weakness, incoordination, hallucinations, confusion, coma. Hypertension, tachycardia, and tachypnea followed by hypotension, bradycardia, and dyspnea, bradypnea can occur. Tachypnea is one of the principle signs nicotine poisoning. Respiratory failure may also occur. Other symptoms can include weak, rapid, and irregular pulse. Vasoconstriction, atrial fibrillation, and sinoatrial block, and ventricular fibrillation have also all been reported. Death is usually from respiratory depression secondary to CNS depression and peripheral blockade of respiratory muscles.[34]

Given the tolerance to nicotine that develops among regular users, a wide range of doses have been shown to lead to acute toxicity. The estimated lethal dose of nicotine is 1 to 13 mg per kilogram of body weight.[35,36] Toxic effects would be seen at much lower levels among the nicotine naïve, such as children, than among established users.

The potential for poisoning is a very real concern for pediatricians, and we fear it is only a matter of time before a child suffers a lethal poisoning from the refill solutions for e-cigarettes. Indeed, liquid nicotine sold to refill e-cigarettes has caused a substantial recent spike in child poisoning, particularly among young children under the age of five. Liquid nicotine is a likely candidate for ingestion by young children because it is colorful, candy flavored and scented, and there is no requirement for child-proof packaging. Given that nicotine is also dermally absorbed, liquid nicotine can be dangerous even if it only comes into contact with the skin. Liquid nicotine is sold in a highly concentrated form, some containing upwards of 36 mg of nicotine per milliliter of liquid nicotine. At this concentration, a small 15 mL dropper bottle of liquid nicotine would contain 540 mg of nicotine. Given the estimated lethal dose range of nicotine, even at the high end of this range this small bottle would contain enough nicotine to kill four 10 kg children (10 kg is an average weight for a one-year-old child).[37] Even a single teaspoon of liquid nicotine at this concentration could kill a small child, and a smaller dose would make one quite ill. In addition, even refill cartridges for e-cigarettes that are self-contained and screw on to the device may also be ingested by small children and create a choking hazard.[38] The CDC reported this year that in the month of February alone, poison control centers received 215 calls related to e-cigarette exposures, many of these in young children.[39] As pediatricians, we are gravely concerned about these risks, and fervently support requiring child-safe packaging for all nicotine containing products.

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[34] Material Safety Data Sheet L-Nicotine. http://www.sciencelab.com/msds.php?msdsId=9926222. Accessed June 16, 2014.

[35] Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Archive of Toxicology*. 2013; 88:5-7.

[36] Bassett RA, Osterhoudt K, Brabazon T. Nicotine Poisoning in an Infant. *New England Journal of Medicine*. 2014; 370:2249-2250.

[37] Testimony of Susanne E. Tanksi, MD, MPH, FAAP. "Aggressive E-Cigarette Marketing and Potential Consequences for Youth." Senate Committee on Commerce, Science, and Transportation. 18 June 2014.

[38] Schraufnagel, D. et al. Electronic cigarettes: A position statement of the Forum of International Respiratory Societies. 30 June 2014. http://www.atsjournals.org/doi/abs/10.1164/rccm.201407-1198PP.

[39] Chatham-Stephens K et al. Calls to poison centers for exposures to electronic cigarettes – United States – September 2010 – February 2014. *Morbidity and Mortality Weekly Report*. Centers for Disease Control and Prevention. 4 Apr. 2014. 63(13); 292-293.

Cigars

Cigars, regardless of their size, have several characteristics that make their potential health effects just as, if not more, dangerous than cigarettes. Due to the fermentation process used to treat cigar tobacco, nitrate in the tobacco leaf is partially reduced and combined with amines to generate significantly higher levels of carcinogenic tobacco-specific N-nitrosamines (TSNAs) in cigar smoke as compared with cigarette smoke.[40] Further, TSNAs are found in higher concentrations in cigar smoke than in cigarette smoke because the wrappers of cigars are less porous than cigarette wrappers.[41] The tar from cigars contain significantly higher levels of ammonia, carbon monoxide, and polycyclic aromatic hydrocarbons, which have been shown to increase the likelihood of cancerous tumor generation in mice.[42] Because of these characteristics, cigars increase the risk for developing chronic obstructive pulmonary disease (COPD), various cancers of the mouth, throat, and lungs, and periodontitis and tooth loss in the primary smoker.[43,44] Secondhand smoke from cigars is also very harmful for children because it contains a high concentration of TSNAs, chemicals, and other carcinogens.

Cigars are very diverse in terms of size, weight, origin, and distribution, in part because cigar weight and size are currently unregulated. Nicotine availability in a cigar is correlated with the amount of tobacco in the cigar, the weight of which can vary from less than 1 gram to more than 20 grams of tobacco leaf. Thus, cigars can deliver a significantly greater amount of nicotine in a shorter period of time to an adolescent than a cigarette, generating the characteristics of nicotine dependence even if the cigar smoke is not inhaled.[45] In addition, nicotine absorption is highly dependent on pH levels. The tobacco used in cigarettes is flue-cured and thus more acidic, which ionizes the nicotine contained in the leaf and makes it less able to cross biological membranes, including the mouth and mucous membranes.[46,47] However, the tobacco found in cigars, as well as pipe tobacco, is more alkaline, allowing the nicotine within cigar smoke to enter the blood stream more quickly, even without primary inhalation of the smoke.[48] Thus, while youth might believe that smoking cigars is less dangerous if the user does not inhale the smoke,

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[40] Baker F et al. Health risks associated with cigar smoking. *Journal of the American Medical Association*. 9 Aug. 2000, 284(6); 735-740.

[41] What about secondhand cigar smoke? American Heart Association. 19 Feb. 2014. http://www.cancer.org/cancer/cancercauses/tobaccocancer/cigarsmoking/cigar-smoking-secondhand-smoke.

[42] Ibid.

[43] Schuster RM. Cigar, cigarillo, and little cigar use among current cigarette-smoking adolescents. *Nicotine & Tobacco Research*. May 2013. 15(5); 925-931.

[44] Albander JM et al. Cigar, pipe, and cigarette smoking as risk factors for periodontal disease and tooth loss. *Journal of Periodontology*. 2000. 71(12); 1874-1881.

[45] Ibid.

[46] Le Houezec J. Role of nicotine pharmacokinetics in nicotine addiction and nicotine replacement therapy: a review. *International Journal of Tuberculosis and Lung Disease*. 2003. 7(9); 811-819.

[47] Benowitz N, Hukkanen J, and Jacob P. Nicotine chemistry, metabolism, kinetics and biomarkers. *Handbook of Experimental Pharmacology*. 2009. (129); 29-60.

[48] Ibid.

the nicotine is still rapidly absorbed into the blood stream, increasing the likelihood of nicotine dependence.

Recently, there has been a marked increase in youth use of cigars, which include premium cigars, large cigars, little cigars, and cigarillos. In 2012, cigar use among high school males exceeded that of cigarette use among high school males at 16.7% and 16.3% respectively.[49] These statistics and others that measure youth use of cigars, however, may underestimate the prevalence of cigars among this population due to incorrect self-identification as a smoker and misidentification of a tobacco product as a cigar, little cigar, or cigarillo.[50,51]

Further, while the Tobacco Control Act set product standards that banned characterizing flavors other than menthol in cigarettes, cigars and cigar-like products are as yet unregulated by the FDA and are able to carry flavors and sweeteners that appeal to children.[52] Flavored cigar use among youth has increased significantly in recent years, especially as a substitute for cigarettes after the ban on characterizing flavors in cigarettes other than menthol by the Tobacco Control Act in 2009. From 1997-2007, little cigar sales increased by 240% with "flavored brands comprising nearly four fifths of the market share" and making up almost half of all convenient store cigar sales by 2011.[53,54] Flavored cigars and little cigars, which come in flavors such as strawberry, grape, and chocolate, are attractive to youth because the flavoring reduces the harshness of smoking.[55] Findings from one study reveal that "more than two fifths of U.S. middle and high school tobacco smokers reported using flavored little cigars…in 2011."[56] This issue of flavorings, in addition to price disparities between cigarettes and cigars due to lower excise taxes and single unit sales, make cigars an attractive tobacco product for use among youth.[57]

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[49] Tobacco product use among middle and high school students – United States, 2011 and 2012. *Centers for Disease Control and Prevention*. 15 Nov. 2013, 62(45); 893-897. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6245a2.htm.

[50] Schuster RM. Cigar, cigarillo, and little cigar use among current cigarette-smoking adolescents. *Nicotine & Tobacco Research*. May 2013. 15(5); 925-931.

[51] Nasim A et al. Cigar use misreporting among youth: Data from the 2009 youth tobacco survey, Virginia. *Preventing Chronic Disease*. 2012. 9:110084.

[52] *Family Smoking Prevention and Tobacco Control Act*. PL 111-31; 123 Stat. 1776. 22 June 2009.

[53] King BA et al. Flavored-little-cigar and flavored-cigarette use among U.S. middle and high school students. *Journal of Adolescent Health*. Jan. 2014. 54(1); 40-46.

[54] Doyle, Kathryn. "Flavored cigars appeal to youth: Study." *Reuters*. 18 Apr. 2014. http://www.reuters.com/article/2014/04/18/us-flavored-cigars-idUSBREA3H0GO20140418.

[55] Preventing tobacco use among youth and young adults: Fact sheet. U.S. Department of Health and Human Services. Office of the Surgeon General. http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/factsheet.html.

[56] King BA et al. Flavored-little-cigar and flavored-cigarette use among U.S. middle and high school students. *Journal of Adolescent Health*. Jan. 2014. 54(1); 40-46.

[57] Delnevo C et al. Trading tobacco: Are youths choosing cigars over cigarettes. *American Journal of Public Health*. Dec. 2005. 95(12); 2123.

Hookah

Youth use of hookahs, also known as waterpipes or narghiles, has recently increased, with 18.5% of high school seniors reporting use in 2011, and over 45% of high school students in one survey indicating that they thought hookah smoking was less harmful than smoking cigarettes.[58,59] Hookah tobacco is available in many different flavors including mint, apple, and cherry that are particularly attractive to children. Hookah tobacco is a combination of tobacco similar to pipe tobacco with honey or molasses and dried fruit, and is not currently regulated and carries a much lower federal tax per pound than cigarette tobacco.[60]

The delivery of nicotine and other chemicals through hookah use is not well measured, and constituent labels for these products and the tobacco sold to fill them tend to be inaccurate regarding the amount of nicotine delivered to the smoker. Further, because hookah smoke is drawn through a water bowl, the harshness of the smoke is lessened, giving the impression that the smoke is less harmful than that of other tobacco products.[61] However, hookah smoke has been linked to a number of deleterious health effects, including lung cancer, respiratory illness, low birth weight, and periodontal disease.[62] Hookah use has also been linked to infectious diseases such as hepatitis, oral herpes, and tuberculosis from infected tobacco.[63,64] In addition, hookah smoking is associated with a high level of smoke inhalation. One study indicated that "a hookah smoker may inhale as much smoke during one standard hookah tobacco smoking session as a cigarette smoker would from 100 cigarettes," and be exposed to more tar and polycyclic aromatic hydrocarbons in one session than a single cigarette.[65]

Dissolvable Tobacco

While the Tobacco Control Act gave the FDA immediate authority over smokeless tobacco products, which are defined as products that "consist of cut, ground, powdered, or leaf tobacco…intended to be placed in the oral or nasal cavity," [66] the proposed

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[58] Morris DS, Fiala SC, Pawlak R. Opportunities for policy interventions to reduce youth hookah smoking in the United States. *Preventing Chronic Disease*. 2012. 9:120082.

[59] Smith JR et al. Determinants of hookah use among high school students. *Nicotine & Tobacco Research*. 31 Mar. 2011; 1-8.

[60] An emerging deadly trend: Waterpipe tobacco use. American Lung Association. Feb. 2007. http://www.lungusa2.org/embargo/slati/Trendalert_Waterpipes.pdf.

[61] Morris DS, Fiala SC, Pawlak R. Opportunities for policy interventions to reduce youth hookah smoking in the United States. *Preventing Chronic Disease*. 2012. 9:120082.

[62] Akl EA et al. The effects of waterpipe tobacco smoking on health outcomes: A systematic review. *International Journal of Epidemiology*. 2010. 39; 834-857. http://ije.oxfordjournals.org/content/39/3/834.full.pdf.

[63] Knishkowy B and Amitai Y. Water-pipe (narghile) smoking: An emerging health risk behavior. *Pediatrics*. July 2005. 116(1); e113-e119.

[64] Fact sheet on hookah smoking. Centers for Disease Control and Prevention. Aug. 2011. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/.

[65] Primack BA et al. US health policy related to hookah tobacco smoking. *American Journal of Public Health*. Sept. 2012. 102(9); e47-e51. http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2012.300838.

[66] *Family Smoking Prevention and Tobacco Control Act*. PL 111-31; 123 Stat. 1776. 22 June 2009.

deeming rule would extend authority to dissolvable tobacco products that do not meet the statutory definition of smokeless tobacco because they may contain nicotine extracted from tobacco leaf.

Dissolvable tobacco as a category is not well defined and may consist of products that either are or are not currently regulated by the FDA by virtue of meeting the existing definition of smokeless tobacco. Dissolvable tobacco products come in many forms with variable nicotine concentrations. At least one company received notice that the FDA did not consider their dissolvable tobacco products to be smokeless products currently under FDA's jurisdiction.[67]

Other companies appear to market dissolvable products that would meet the smokeless tobacco definition. Companies such as R.J. Reynolds have introduced several different dissolvable products in pellet, stick, and strip form that deliver a concentrated amount of nicotine over a short period of time in a variety of flavors attractive to children, including orange and mint.[68] Camel Orbs, which are the size of small mints, contain 1 mg of nicotine per pellet, a potentially lethal dose of nicotine for a small child. These products have a high average pH similar to cigar and pipe tobacco, greatly increasing the amount of absorbable nicotine in these products compared with cigarettes or snuff tobacco.[69] While these products also have child resistant packaging, it may be common for adults to remove more than one pellet, strip, or stick at a time for convenience, leaving these dissolvable products within easy reach of children. Further, awareness of these products is higher in lower age groups, and unlike some other smokeless tobacco products, cigarette-and never-smokers are equally likely to be aware of these products.[70]

Dissolvable products could be mistaken not only for candy but also for FDA-approved nicotine replacement therapies, despite that the fact that they have not been studied for safety or efficacy in smoking cessation. Because little research has been done on the hazards of these products, their ability to generate early nicotine addiction, their ability to reduce smoking cessation by providing a smokeless alternative, and because these products have historically posed a poisoning risk to children, we have significant health concerns about the impact of dissolvable tobacco products on children and the public health.

Nicotine Gels

Nicotine gel is a hand gel similar in consistency to antibacterial hand gel that delivers nicotine transdermally after being rubbed on the hands. As shown with transdermal

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[67] http://articles.latimes.com/2011/mar/25/news/la-pn-tobacco-lozenges-fda-20110325

[68] Connolly GN et al. Unintentional child poisonings through ingestion of conventional and novel tobacco products. *Pediatrics*. 125(5); 896-899.

[69] Ibid.

[70] Regan AK, Dube SR, and Arrazola R. Smokeless and flavored tobacco products in the U.S. *American Journal of Preventive Medicine*. 2012. 42(1); 29-36.

nicotine patches, a form of nicotine replacement therapy (NRT), nicotine is highly absorbable through the skin, and studies have shown children and young adults to be more susceptible to the effects of nicotine poisoning through transdermal absorption than adults.[71] As with liquid nicotine, nicotine gel poses significant risks for children when ingested or spilled on the skin. Currently, these gels are not sold as a form of NRT and are not FDA-approved as cessation products. We urge the FDA to take proper steps to regulate these products and to apply child-proof packaging standards to these products to prevent nicotine poisoning in children.

Pipe Tobacco

Pipe tobacco has similar pH and nicotine levels to cigar tobacco because it is cured using the same process.[72] Thus, children and adolescents who use pipes are at a risk for nicotine dependence through oral absorption of high levels of nicotine. Pipe tobacco, like cigars, is also typically smoked over long periods of time, releasing significant amounts of secondhand smoke into the environment. As with other unregulated tobacco products, pipe tobacco is sold in a variety of flavors that are appealing to children and gives off strong smells when combusted that are attractive to children.

Other Novel Tobacco Products

The FDA is proposing extending its jurisdiction to any product the meets the statutory definition of tobacco product, which would include any future novel tobacco product. Any new product "made or derived" from tobacco is likely to have health implications for children and the public. The presence of nicotine in a product, regardless of the form it takes or how it is delivered to the user, is reason enough to have significant health concerns.

Expanding Basic Authorities to All Tobacco Products, Including All Cigars

While the Tobacco Control Act only gave the FDA immediate authority over cigarettes, smokeless tobacco, and roll-your-own tobacco, the law allows the FDA to expand its jurisdiction to additional types of tobacco products through rulemaking. In the proposed rule, the FDA proposes to deem all types of tobacco products (with the possible exception of large and premium cigars) subject to the Food, Drug and Cosmetic Act. In the rule, the FDA refers to newly deemed tobacco products as "covered tobacco products.")

For the reasons described above, the AAP strongly believes that all products meeting the statutory definition of tobacco product ("any product made or derived from tobacco that is intended for human consumption…" but excluding any drug or medical device) should be subject to at least the basic regulatory authorities established under the Tobacco

[71] McBride J et al. Green tobacco sickness. *Tobacco Control*. Sept. 1998. 7(3); 294-298.
[72] Benowitz N, Hukkanen J, and Jacob P. Nicotine chemistry, metabolism, kinetics and biomarkers. *Handbook of Experimental Pharmacology*. 2009. (129); 29-60.

Control Act. All tobacco products contain nicotine and, as such, have important implications for public health. Therefore, regardless of the relative health risks posed to an individual user by any particular product, all tobacco products should be deemed subject to the Tobacco Control Act.

Arguments against extending FDA regulation to all or certain types of tobacco products generally consist of claims that (1) regulation will be harmful to tobacco manufacturers, particularly small businesses, and/or that (2) certain types of tobacco products are less harmful than other types of tobacco products (such as cigarettes). In our view, neither of these claims is a valid reason for not expanding basic jurisdiction to additional classes of tobacco products. Any company in the business of selling tobacco products, whether small or large, must be required to abide by a regulations put in place for the protection of children and the public health. Regulatory decisions related to tobacco products must be made on the basis the risk posed to the public, not on the size of the company manufacturing the product.

In addition, the FDA does have the authority regulate different tobacco products in different ways if the science supports such an approach. Therefore, it would be inappropriate to fail to deem a particular type of tobacco product subject to the Food, Drug and Cosmetic Act even if that product posed different public health questions than currently regulated products. Leaving the FDA wholly without the authority to regulate certain classes of products would leave a huge regulatory loophole that could be easily exploited by tobacco manufacturers.

Deeming all tobacco products subject to the Food, Drug and Cosmetic Act is important to ensure that the basic tobacco control authorities granted to the FDA apply to tobacco without exception. These basic authorities include: (1) enforcement action against products determined to be adulterated and misbranded; (2) required submission of ingredient listing and reporting of harmful and potentially harmful constituents (HPHCs); (3) required registration and product listing; (4) prohibition against use of modified risk descriptors (e.g., "light," "low," and "mild" descriptors) and fraudulent health claims unless FDA issues an order permitting their use; (5) prohibition on the distribution of free samples; and (6) premarket review requirements.

Each of these basic authorities serve essential public health functions. The FDA's misbranding authority is a crucial regulatory authority that gives the FDA the power to remove a product from the market if it is not in compliance with the law. Requiring the submission of all ingredients and harmful constituents in a tobacco product is absolutely necessary to be able determine the health effects of using that product. Registration and product listing is important for understanding the full universe of tobacco products on the market. The use of modified risk descriptors or claims unsupported by evidence can cause serious harms, as in the case "light" cigarettes which were proven not to be any

healthier than regular cigarettes.[73] Free sampling has historically been used to attract and addict children and non-smokers to tobacco and is never an appropriate practice.[74] Finally, the premarket review provisions put in place by the Tobacco Control Act prevent (1) the entry to new products on the market unless shown to benefit the public health, and (2) the modification of existing tobacco products in ways that would make them more dangerous to the public.

Proposed Cigar Exemption

The proposed rule offers two options for deeming cigars subject to the Food, Drug and Cosmetic Act. Option 1 would deem all tobacco products, including all cigars, subject to the Food, Drug and Cosmetic Act. Option 2 would deem all tobacco products with the exception of what the proposal terms "premium cigars." A premium cigar would have to meet the following criteria: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units.

We strongly urge the FDA to reject Option 2 and deem all cigars subject to the Food, Drug and Cosmetic Act. As described above, cigars have very real health consequences (both to users as well as non-users in the form of secondhand smoke) and use rates among youth have been rising in recent years. Creating any type of loophole for certain cigars would allow cigar manufacturers to circumvent regulatory safeguards designed to protect the public. It also sets a dangerous precedent that the way to appropriately regulate different tobacco products with different characteristics is to regulate some and to completely fail to regulate others. The FDA would have the authority to assert jurisdiction over all cigars and differentially apply tobacco control provisions to certain cigars if shown to be appropriate based on scientific evidence. Therefore, it is unnecessary and inappropriate to completely exempt premium cigars from the Food, Drug and Cosmetic Act.

We also note that a redline document added to the docket clearly shows that the proposal to exclude premium cigars from regulation came not through the FDA's science-driven regulatory development process, but was rather added during review of the proposed rule by the Office of Management and Budget. We view this is as inappropriate political

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[73] "Light" cigarettes and cancer risk. National Cancer Institute. National Institutes of Health. 28 Oct. 2010. http://www.cancer.gov/cancertopics/factsheet/Tobacco/light-cigarettes.

[74] Mejia AB and Ling PM. Tobacco industry consumer research on smokeless tobacco users and product development. *American Journal of Public Health*. Jan. 2010. 100(1); 78-87.

interference in what should be an evidence-based process and further evidence that Option 2 is inappropriate for the protection of public health.

If the FDA does choose to exclude premium cigars from the final rule, we strongly recommend that the FDA and the administration not in any way broaden the definition of premium cigar beyond the current proposal. Particularly important to retain would be the $10 price point per cigar and the prohibition on flavors other than tobacco. Adolescents are particularly price sensitive, and as such keeping the price of unregulated cigars as high as possible ($10 or perhaps higher) would be paramount.[75] We also know that flavored tobacco products are particularly appealing to children, so in no case would it be appropriate for an unregulated cigar to be sold in a flavor other than tobacco.

Warning Labels

The proposed rule requires a new warning label regarding the addictiveness of nicotine on loose cigarette tobacco, roll-your-own tobacco, and all newly deemed tobacco products (which would include e-cigarettes, hookah, pipe tobacco, certain dissolvables, and gels). The FDA proposes the warning label to read: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." The AAP strongly supports the proposed warning. Any tobacco product that contains nicotine poses some degree of addiction potential. Any time a product contains nicotine, it is important to alert consumers as to the nicotine content and remind them that nicotine is a highly addictive substance. A nicotine warning is particularly important for novel tobacco products such as e-cigarettes, which consumers—and children in particular—may not understand contain tobacco. Historically, comprehensive warning labels, especially those that are clearly worded and invoke an emotional response, are effective in preventing tobacco initiation by youth.[76]

For cigars, the proposed rule proposes to institute a series of five required rotating warnings. The warnings consist of five of the six total warnings that the seven largest cigar companies agreed to include in their packaging and advertising in a settlement with the Federal Trade Commission in 2000.

The five warnings are as follows:

(1) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.

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[75] Delnevo C et al. Trading tobacco: Are youths choosing cigars over cigarettes. *American Journal of Public Health.* Dec. 2005. 95(12); 2123.

[76] Riordan M. Tobacco warning labels – evidence of effectiveness. Campaign for Tobacco-Free Kids. 19 Mar. 2013. http://www.tobaccofreekids.org/research/factsheets/pdf/0325.pdf.

(2) WARNING: Cigar smoking can cause lung cancer and heart disease.

(3) WARNING: Cigars are not a safe alternative to cigarettes.

(4) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

(5) WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.

The FDA is proposing to not include the sixth warning, specifically: "Tobacco use increases the risk of infertility, stillbirth and low birth weight." The FDA explains that "although cigarette smoking has been shown to cause these health effects and cigar smoke is similar, the Agency is not aware of studies specifically linking cigars to these reproductive effects." In the medical opinion of the American Academy of Pediatrics, it would be appropriate for the FDA to scientifically infer that similar smoke would produce similar health consequences, even if, in general, smoking behaviors among cigar smokers and cigarette smokers do differ somewhat. Therefore, the AAP recommends that all six warnings in the 2000 FTC consent order be required to be rotated on cigar packaging and advertisements.

We strongly recommend that the FDA require a warning label on any liquid nicotine product based on the high degree of risk these products pose to young children. Such a warning could regard: "WARNING: Keep out of reach of children. This product is highly toxic and could cause serious injury or death, particularly in young children, if ingested or upon contact with the skin." In addition, we recommend that the FDA consider requiring child poisoning warning labels for other tobacco products based on the comprehensive child poisoning risk assessment that we recommend FDA undertake later in these comments.

Sales Restrictions

Purchase Age Restrictions

Currently, only 38 states have issued prohibitions on the sale of e-cigarettes to individuals under the age of 18.[77] As such, the need for a national purchase age for all tobacco products is self-evident. It is completely unacceptable for any tobacco product of any kind to be ever sold to a child. Deeming e-cigarettes subject to the Food, Drug and Cosmetic Act and extending the purchase age restriction to these products nationally is a simple and commonsense measure to keep tobacco out of the hands of children and reduce adolescent tobacco initiation.

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[77] Alternative nicotine products: Electronic cigarettes. National Conference of State Legislatures. 16 July 2014. http://www.ncsl.org/research/health/alternative-nicotine-products-e-cigarettes.aspx.

It is important to note that no vaporizing device—whether designed for vaporizing liquid nicotine, non-nicotine solution or whole tobacco—has been proven to be safe in the pediatric population. Even absent nicotine, there are potential negative health consequences associated with inhaling the vapor of electronic cigarettes into the still-developing lungs of a child. In addition, there is a serious risk that if non-nicotine containing vaporizing devices were allowed to be sold to children, that they would serve as starter products for youth that may eventually lead them to try nicotine-containing products or even traditional cigarettes. Therefore, the AAP would support purchase age restrictions for all vaporizing products, including those designed for liquid and whole leaf vaporization. The FDA should institute purchase restrictions for those under the age of 18 for all e-cigarettes and vaporizing devices that meet the definition of "tobacco product" or "component, part, or accessory of a tobacco product…" under the Tobacco Control Act.

Prohibition on Vending Machine Sales

The Academy's official tobacco control policy statement supports banning the unsupervised sale of tobacco products to youth, including vending machine sales.[78] Substantial evidence suggests that youth are able to gain access to tobacco products from vending machines far more easily than through over-the-counter sales, even when using lockout devices and requiring human interaction after a lockout indication has been given.[79] Further, tobacco product vending machines without location restrictions also increase the burden of enforcing underage sales restrictions.[80] We support FDA's proposed regulation that would ban vending machine sales of covered tobacco products, except in facilities where individuals under the age of 18 are not permitted at any time.

Self-Service Displays

The AAP's tobacco control policy also does not support the use of self-service displays for any tobacco products and urges behind-the-counter sales only.[81] While the Tobacco Control Act bans the sale of cigarettes and smokeless tobacco products unless through a direct, face-to-face exchange with the retailer (which requires the retailer to directly hand a product to the customer at the customer's request), the proposed deeming rule does not make the same restriction for covered tobacco products.[82] It has been shown that stores with self-service displays at the counter are 40% more likely to experience shoplifting by youth, with one study indicating that "up to 50% of youth smokers have shoplifted

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[78] Tobacco use: A pediatric disease. *Pediatrics*. 2009. 124(5); 1474-1487. http://pediatrics.aappublications.org/content/124/5/1474.full.pdf+html.

[79] Youth access to tobacco: The effects of age, gender, vending machine locks, and "it's the law" programs. *American Journal of Public Health*. Feb. 1996. 86(2); 221-224.

[80] Ibid.

[81] Tobacco use: A pediatric disease. *Pediatrics*. 2009. 124(5); 1474-1487. http://pediatrics.aappublications.org/content/124/5/1474.full.pdf+html.

[82] 21 C.F.R. §1140.16(c).

cigarettes at least once."[83] We believe that equating covered tobacco products with the same self-service display standards as cigarettes and smokeless tobacco products, especially with electronic items such as e-cigarettes that have a higher comparable retail value than many other tobacco products, is important for enforcing tobacco product age restrictions, preventing theft, and preventing stolen items from finding their way into the hands of impressionable children. Many e-cigarettes also contain the nicotine equivalent of one or more packs of traditional cigarettes in a relatively small size, making it possible for children to quickly shoplift a high quantity of nicotine and easily conceal the product.

Minimum Pack Size

The Tobacco Control Act clearly bans the sale or redistribution of cigarettes packaged in quantities of less than 20, which is the minimum cigarette package size defined in the law.[84] However, the deeming rule does not propose any minimum package size standards for cigars. Minimum package size requirements dissuade youth smokers by increasing the unit price of tobacco products. Minimum package size requirements have been shown to reduce youth usage and initiation of cigarettes and smokeless tobacco, while the use of other tobacco products have risen over the past decade and will continue to rise without similar packaging standards.[85] For these reasons, we request that the FDA develop a minimum package size standard for cigars comparable to the current standards for cigarettes.

Age Verification for Internet Sales

While the proposed deeming rule requires warning labels to appear on covered tobacco products sold over the internet, the rule does not include any requirements for age verification of internet sales. The popularity of e-cigarettes and other covered tobacco products has increased dramatically due in no small part to Internet advertising of these products and the ease with which youth can purchase these products, including covered tobacco products with no child-proof packaging standards, online without age verification. We believe that Internet sales for covered tobacco products offers a significant pipeline for youth tobacco initiation and should be banned completely, unless the FDA develops a highly effective system for age verification at least as comprehensive and stringent as the age verification for internet sales of cigarettes and smokeless tobacco products contained in the *Preventing All Cigarette Trafficking (PACT) Act*. The *PACT Act* standards require Internet tobacco product merchants to: (1) pay all applicable federal, state, and local tobacco taxes before delivering merchandise; (2) comply with the same state and local laws as those in the customer's location; (3) and check the age and

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[83] Ibid.

[84] 21 C.F.R. §1140.16(b).

[85] Regulating tobacco products based on pack size. Tobacco Control Legal Consortium. Feb. 2012. http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regulating-packsize-2012_0.pdf.

identification of customers at both purchase and delivery to ensure that no customer is violating federal or state age restrictions for tobacco product purchase.[86]

Marketing Restrictions

Sports/Event Sponsorships

The Tobacco Control Act required the FDA to put in place regulations, made effective in 2010, that prohibit any manufacturer or distributor from placing cigarette or smokeless tobacco product advertisements within the promotional materials for any athletic, musical, cultural, or team event. However, the proposed deeming rule does not address a similar ban for covered tobacco products.[87] Historically, tobacco companies have used sports marketing of their products as a means of circumventing advertising bans over the past several decades, and as a means of attracting a diverse audience that includes children and adolescents into using tobacco products.[88] Indeed, the harms to children of the marketing of enticing tobacco products are enhanced by giving children the idea that athletic excellence and tobacco use are strongly linked, reinforcing the notion that tobacco product use is popular.[89] Indeed, a recent study released by several members of Congress identified that the top e-cigarette manufacturers were sponsoring social, athletic, and cultural events targeting their products specifically at youth and had been doing so for several years.[90] We are disappointed that the FDA has not yet addressed the issue of sports and event sponsorships and tobacco product advertisements for covered tobacco products and urge the FDA to develop the same advertising bans that currently apply to cigarettes and smokeless tobacco products.

Cartoons and Celebrities

The Tobacco Control Act gives the FDA the authority to institute advertising restrictions to promote the public health.[91] The manufacturers of unregulated tobacco products are currently using the same advertising tactics that big tobacco used prior to the Master Settlement Agreement (MSA) including celebrity promotions and cartoon advertisements in print media that are specifically attractive to impressionable children.[92] E-cigarettes

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[86] *Prevent All Cigarette Trafficking Act of 2009*. PL 111-154. 124 Stat. 1087. http://www.gpo.gov/fdsys/pkg/PLAW-111publ154/pdf/PLAW-111publ154.pdf.

[87] 21 C.F.R. §1140.24(c).

[88] Dewhirst T and Hunter A. Tobacco sponsorship of formula one and CART auto racing: Tobacco brand exposure and enhanced symbolic imagery through co-sponsors' third party advertising. *Tobacco Control*. 2002. 11; 146-150.

[89] Tobacco advertising and youth: Marketing tactics. Campaign for Tobacco-Free Kids. 2008. http://global.tobaccofreekids.org/files/pdfs/en/APS_youth_tactics_en.pdf.

[90] Senators Durbin, Harkin, Rockefeller, Blumenthal, Markey, Brown, Reed, Boxer, Merkley, Representatives Waxman and Pallone. Gateway to addiction: A survey of popular electronic cigarette manufacturers and targeted marketing to youth. 14 Apr. 2014. http://democrats.energycommerce.house.gov/sites/default/files/documents/Report-E-Cigarettes-Youth-Marketing-Gateway-To-Addiction-2014-4-14.pdf.

[91] *Family Smoking Prevention and Tobacco Control Act*. PL 111-31; 123 Stat. 1776. 22 June 2009.

[92] Testimony of Susanne E. Tanksi, MD, MPH, FAAP. "Aggressive E-Cigarette Marketing and Potential Consequences for Youth." Senate Committee on Commerce, Science, and Transportation. 18 June 2014.

and other covered tobacco products have succeeded in rapidly expanding their market penetration to children, with one e-cigarette company's advertisements reaching over 17 million 12-17 year olds in less than a six month period in 2013.[93] Some of these advertisements glamorize e-cigarette use by including cartoon characters such as Popeye and actors and actresses that have recently starred in movies designed specifically for children and youth audiences such as Harry Potter.[94] We urge the FDA to address the issue of cartoon and celebrity advertising and to the maximum extent permitted by the First Amendment to the Constitution, prevent aggressive marketing of covered tobacco products that is appealing to children and youth for the protection of the public health.

Non-Tobacco Merchandise Logos Used to Promote Tobacco Products

Liquid nicotine and other novel tobacco products are being sold under the trade names of other products consumed by children, such as Cap'n Crunch and Scooby Snacks, in many cases probably without the permission of those trademark holders. The Tobacco Control Act required that the FDA reissue a 1996 final rule restricting the sale and distribution of cigarettes, roll-your-own, and smokeless tobacco products, which became final June 22, 2010.[95] The final rule prohibits the use of non-tobacco trade or brand names as a brand or trade name of a tobacco product regulated under the Tobacco Control Act unless that tobacco product was marketed under the non-tobacco trade or brand name before June 22, 2009.[96,97] However, the proposed deeming rule does not propose to extend this prohibition to include covered tobacco products, allowing tobacco companies to market novel tobacco products in flavors and themes of current food and candy products that are designed to be attractive to children. We urge the FDA to amend the language of this section to include covered tobacco products.

Tobacco Logos on Non-Tobacco Merchandise

In the same reissued 1996 final rule mentioned previously that restricted the sale and distribution of cigarettes, roll-your-own, and smokeless tobacco products, the FDA prohibited the marketing or promotion of non-tobacco merchandise containing tobacco product brand names.[98] However, the proposed deeming does not propose to extend this prohibition to include covered tobacco products, and we urge the FDA to amend the language of this section to include covered tobacco products to prevent children from receiving non-tobacco materials (such as free giveaways) containing tobacco product brands.

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[93] Ibid.

[94] "Aggressive E-Cigarette Marketing and Potential Consequences for Youth." Hearing of the Senate Committee on Commerce, Science, and Transportation. 18 June 2014. http://www.commerce.senate.gov/public/index.cfm?p=Hearings&ContentRecord_id=42af91a8-6308-45b5-9842-74bc5833be73&ContentType_id=14f995b9-dfa5-407a-9d35-56cc7152a7ed&Group_id=b06c39af-e033-4cba-9221-de668ca1978a&MonthDisplay=6&YearDisplay=2014.

[95] 21 C.F.R. §1140.16(a).

[96] Ibid.

[97] Ibid.

[98] 21 C.F.R. §1140.34.

Television Advertising

Cigarette advertising in television and radio was banned in 1971 in part to curb tobacco exposure to youth.[99] Manufacturers of covered tobacco products are using their unregulated status to use flashy television advertisements and well-researched media placement to specifically target children and young adults with their products. A recent Senate report indicated that the top e-cigarette manufacturers issued radio and television ads during sporting and promotional events that are widely watched by children, including the Super Bowl, which had over a 30% viewership among teens and over a 20% viewership among children aged 2-11.[100] These companies also advertised during popular television shows with age-diverse viewership on channels such as AMC and Comedy Central, perpetuating the notion that using tobacco products is cool and glamorizing the idea of tobacco use at an unacceptably early age.[101] We were disappointed that television advertising was not addressed in the proposed deeming rule and urge that the FDA develop standards, consistent with the First Amendment, to reduce child exposure to television advertisements for covered tobacco products.

Product Standards

Flavored Tobacco Products

The appeal of flavored tobacco products to youth is well known. We know from the traditional cigarette example that flavors increase smoking initiation among youth, which led to the ban of all characterizing flavors (other than menthol) in cigarettes under the Tobacco Control Act. Historically, flavored tobacco products "tend to contain lower levels of free nicotine and pH, features which are characteristic of initiation products."[102] In addition, children and adolescents are more prone to be attracted to flavors that may be or appear to be sweet, increasing the likelihood that fruit and other sweet flavors will attract younger users.[103] Flavors are widely used in cigars, e-cigarettes, and hookah.

The appeal of flavors to children is also well understood by e-cigarette manufacturers, for one. A parent education website sponsored by one e-cigarette company notes that "kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors

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[99] *Smoking and Tobacco Use*. Centers for Disease Control and Prevention. http://www.cdc.gov/Tobacco/.

[100] Senators Durbin, Harkin, Rockefeller, Blumenthal, Markey, Brown, Reed, Boxer, Merkley, Representatives Waxman and Pallone. Gateway to addiction: A survey of popular electronic cigarette manufacturers and targeted marketing to youth. 14 Apr. 2014. http://democrats.energycommerce.house.gov/sites/default/files/documents/Report-E-Cigarettes-Youth-Marketing-Gateway-To-Addiction-2014-4-14.pdf.

[101] Ibid.

[102] Kostygina, G et al. FDA should prohibit flavors in all tobacco products in the current rule making. Center for Tobacco Control Research and Education, University of California San Francisco. 30 May 2014. http://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-comment-deeming%20rule%20flavor%20comment%20June3AAA-1jy-8chl-vs81.pdf.

[103] De Graaf C and Zandstra EH. Sweetness intensity and pleasantness in children, adolescents, and adults. *Physiology and Behavior*. 1999 Oct; 67(4): 512-20.

such as cherry, vanilla, piña-colada and berry."[104] Despite understanding that these products appeal to children, that same company markets e-cigarettes in cherry, vanilla, piña colada and other candy flavors. Furthermore, liquid nicotine comes in flavors like "cotton candy" and "gummy bear," which seem clearly designed to entice new youth users. In addition, the chemicals used to flavor liquid nicotine and a variety of other currently unregulated novel tobacco products are the same chemicals used to flavor candy and soft drinks that appeal to children, such as 1-hexanol, which was detected in apple flavored candy and all apple-flavored tobacco products tested in one study.[105]

The flavorings themselves are also cause for concern on multiple levels. There is limited data regarding the safety of vaporizing the chemical characterizing flavors, and there may be risks of flavorings to the user directly. One study indicated that embryonic and newborn lung cells were sensitive to flavored vapor and that cytotoxicity and developmental issues occurred in these cells even when the flavored liquid did not contain nicotine.[106]

As recognized in the proposed deeming rule, under the Tobacco Control Act, the FDA has the regulatory authority to institute tobacco product standards such as a prohibition the use of flavors in tobacco products, if such restrictions are appropriate for the protection of public health.[107] We are disappointed that the FDA has not proposed a product standard to prohibit flavors in covered tobacco products, and urge the FDA to immediately address the use of flavors, which are clearly designed to be attractive to children.

Reducing Child Poisoning Related to Tobacco Products

For reasons cited above, there is an urgent need for the FDA to take immediate action to prevent child poisoning and death related specifically to liquid nicotine products. In addition, we recommend that the FDA conduct a science-based assessment of the risks of child poisoning for each other type of tobacco product under its jurisdiction, including but not limited to dissolvable tobacco and tobacco gel. This assessment should include the participation of experts in toxicology and poison prevention. Based on this assessment, any additional types of tobacco products that are determined to have a significant risk of causing harm to children through accidental exposure (whether related to ingestion or other exposures such as dermal absorption) should be subject by action by the FDA to reduce the risk to children.

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[104] Lorillard Inc. Youth Smoking Prevention Program. What you need to know about e-cigarettes – Infographic. Available at http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/. Accessed June 16, 2014.

[105] Brown J et al. Candy flavorings in tobacco. *New England Journal of Medicine*. 2014; 370: 2250-2252. http://www.nejm.org/doi/full/10.1056/NEJMc1403015?query=featured_home.

[106] Bahl V et al. Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. *Reproductive Toxicology* 2012; 34: 529-537.

[107] *Family Smoking Prevention and Tobacco Control Act*. PL 111-31; 123 Stat. 1776. 22 June 2009.

The AAP has endorsed the Child Liquid Nicotine Poisoning Prevention Act (S. 2581), a bill that would allow and require the Consumer Product Safety Commission (CPSC), which is currently prohibited from regulating any tobacco products under consumer product safety law, to issue rulemaking requiring child-resistant packaging on "liquid nicotine containers." Our endorsement of this legislation should not be construed to mean that we believe that the FDA either lacks the authority to require child-resistant packaging or is not an appropriate agency to take such action. In fact, S. 2581 has clear language preserving the authority of the FDA to regulate "the manufacture, marketing, sale, or distribution of liquid nicotine, liquid nicotine containers, electronic cigarettes, or similar products that contain or dispense liquid nicotine."

We believe that the FDA clearly has the authority under Sec. 907 of the Food, Drug and Cosmetic Act to institute tobacco product standards related to reducing child poisoning, as such standards would be appropriate and even necessary for the protection of the public health. However, the AAP was seriously disappointed that the FDA failed to propose child-resistant packaging in this proposed rule. Because we view child poisoning from liquid nicotine as an urgent child health issue, we have encouraged Congress to swiftly address the issue of liquid nicotine through legislation given uncertainty regarding the ability of the FDA to address this issue quickly through the regulatory process. If S. 2581 or similar legislation is signed into law, we believe that the FDA and CPSC can and should exercise concurrent jurisdiction on this issue. Narrow CPSC action related to child-resistant packaging for liquid nicotine products should not constrain the FDA from instituting a more comprehensive approach to preventing accidental exposure to all risky tobacco products.

We strongly encourage the FDA to propose tobacco product standards to reduce the risk of harm due to accidental exposure for liquid nicotine products and any other products the FDA determines pose a threat to young children. In crafting such tobacco product standards, the FDA should consider the following:

(1) Child-resistant packaging: We recommend that the FDA require child-resistant packaging consistent with the established standards for child-resistant packaging established by the Consumer Product Safety Commission.

(2) Flow restriction: For liquid-based products, the FDA should consider limiting the allowable speed of flow of the product from its container. This could be accomplished in various ways including requiring a flow-restricting device on the opening of a container or requiring a rigid container to prevent quick dispensing of a product by squeezing the container.

(3) Concentration/quantity limitation: The FDA should consider limiting the allowable concentration of nicotine in liquid-based tobacco products. The FDA should also consider

limiting the allowable total nicotine content in an individual container to a non-lethal amount for a small child.

In addition to seeking product standards, we also urge the FDA to include consideration of child poisoning in its consideration of PMTAs. The FDA should seek information about packaging from PMTA applicants and should reject any PMTA for a tobacco product that would be sold without measures to reduce child poisoning if that product poses a significant risk to children from accidental exposure.

Mislabeling of Cigarettes as Cigars

As mentioned previously, consumers of cigars, especially youth, frequently misidentify cigars. Little cigars and cigarillos frequently come in small sizes, and current legal code defining both cigarettes and cigars is vague regarding differentiation between the two products in terms of size, appearance, and wrapper composition.[108] Section 907(a)(1)(A) of the Tobacco Control Act prohibits the addition of characterizing flavors other than menthol in cigarettes. This prohibition is important for child health because flavored tobacco products have been shown to be attractive to youth and increase smoking initiation. We have become aware that some cigarette products have been attempting to circumvent this flavor prohibition by incorporating tobacco leaf into the product's wrapper and labeling the product as a cigar rather than a cigarette. However, since these products share similar characteristics to cigarettes in terms of size and packaging, they are consistent with a "roll of tobacco wrapped in any substance containing tobacco which, because of its appearance…is likely to be…purchased by, consumers as a cigarette," which under the Food, Drug and Cosmetic Act and the Federal Cigarette Labeling and Advertising Act are legally a cigarette. The FDA should clarify that these products are indeed cigarettes in disguise and should act to prohibit the addition of flavors to these products.

Compliance Period and Effective Date

The proposed rule would institute a 24-month compliance period during which manufacturers of newly deemed types of tobacco products would not have to submit to FDA justification for their continued presence on the market. The FDA is charged with ensuring that no new tobacco products enter the US market after February 15, 2007 unless those products are either found to benefit the public health or to be substantially equivalent to a product on the market before that date. Allowing such a long compliance period allows potentially harmful products to remain on the market for at least two years after the effective date of the final rule, regardless of if there is evidence that such products may pose a danger to the public health. For new products, particularly those seeking approval through the PMTA pathway, the evidentiary burden is clearly on the

[108] 26 U.S.C. §5702(a-b).

manufacturer to justify the continued sale of its products on the basis of public health benefit. A 24-month compliance period inappropriately gives manufacturers the benefit of the doubt for two years, and would even allow products with no intention of submitting a PMTA or a substantially equivalent report to remain on the market. While it is understandable to provide manufacturers a reasonable amount of time to respond to the requirements of the final rule, a one-year compliance period would be sufficient to allow the preparation of the appropriate documents to justify marketing. We recommend reducing the compliance period to 12 months.

In addition, we believe that in no circumstances would it be appropriate to allow any compliance period for a refillable liquid nicotine product sold without child-resistant packaging. As discussed earlier in these comments, nicotine is a highly toxic substance and is particularly dangerous to children when sold in liquid form. Manufacturers of liquid nicotine that have such little regard for the safety of young children that they fail to put in place commonly-accepted and easily-adopted measures to prevent child poisoning through accidental ingestion deserve no compliance period from the FDA. We urge the FDA to recognize the urgency of this real threat to public health and to exercise no enforcement discretion with respect to refillable liquid nicotine sold without child-resistant packaging. Further, we urge the FDA not to grant a compliance period of any length for products sold in characterizing flavors other than tobacco or any covered tobacco products that use marketing practices known to appeal to children and youth.

We also urge the FDA to finalize the proposed deeming regulation without delay. In no case should the FDA publish a final rule to assert jurisdiction over all tobacco products later than one year after the publication of the proposed rule. We call on the FDA to finalize this rule as soon as possible, but no later than April 25, 2015. The quickness of the development of nicotine addiction in adolescents makes it imperative that the FDA act as soon as possible to prevent the establishment of new lifetime tobacco users. It may be appropriate for the FDA to address issues related to marketing and product standards for newly deemed products in separate rulemaking, outside of the context of this proposed rule. If the FDA chooses to do so, it should publish a proposal to do so as soon as possible, so that such regulations could be finalized at the same time as the deeming rule is finalized.

Cost-Benefit Analysis and Consumer Surplus

As with the final rule requiring graphic warning labels on tobacco products effective in 2011, the FDA performed a cost-benefit analysis of the regulatory actions proposed in the deeming rule, quantifying the savings that would occur through the public health benefits of regulating all tobacco products.[109, 110] Such potential savings were specifically

[109] *Family Smoking Prevention and Tobacco Control Act*. PL 111-31; 123 Stat. 1776. 22 June 2009.
[110] Required Warnings for Cigarette Packages and Advertisements. *Food and Drug Administration*. Federal Register. 21 C.F.R. §1141. Docket No. FDA-2010-N-0568.

mentioned in the Tobacco Control Act, quantifying, for instance, that a reduction in youth smoking by 50% would yield $75 million in savings related to reduced health care costs.[111] However, the deeming rule incorporated only a 30% welfare gain ratio, translating into a 70% downward adjustment in savings by factoring in estimated consumer surplus loss, or the loss of pleasure from smoking when a tobacco user quits smoking.[112]

Consumer surplus is based on rational choice theory, with individuals carefully and rationally calculating that, in this case, the perceived future costs of purchasing and using tobacco products would be less than the present benefits of smoking.[113] The FDA in its final rule argued that smoking has a significant and positive consumer surplus because of a customer's willingness to pay more for cigarettes than their actual monetary value.[114] Further, the FDA cited that cigarette smoking is pleasurable, and that consumer surplus used in their calculations is grounded in the concept of willingness-to-pay within an economic model that involves rational choice theory.[115]

As introduced above, the concept of rational choice theory "assumes stable preferences…and adequate cognitive abilities to make the decision to start or continue smoking."[116] However, individuals that use tobacco products are operating in anything but a completely rational economic environment. As mentioned previously, nicotine is a highly addictive substance. Extensive literature in the field of behavioral economics has established that addictive products produce a conflict between how an individual chooses to act in the present time with how an individual perceives his or her ability to choose in the future, i.e. the ability to quit using tobacco products.[117] Further, long-term consequences from using addictive tobacco products overwhelmingly start in childhood and adolescence, where youth are less able to make rational decisions about the future

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http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM339834.pdf.

[111] *Family Smoking Prevention and Tobacco Control Act*. PL 111-31; 123 Stat. 1776. 22 June 2009.

[112] Deeming tobacco products to be subject to the food, drug, and cosmetic act, as amended by the family smoking prevention and tobacco control act; regulations restricting the sale and distribution of tobacco products and required warning statements for tobacco product packages and advertisements: Preliminary regulatory impact analysis; initial regulatory flexibility analysis; unfunded mandates reform act analysis. Docket No. FDA-2014-N-0189. 24 Apr. 2014; 52.

[113] Song, AV, Brown P, Glantz SA. When health policy and empirical evidence collide: The case of cigarette package warning labels and economic consumer surplus. *American Journal of Public Health*. 12 Dec. 2013. http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2013.301737.

[114] Ibid.

[115] Required Warnings for Cigarette Packages and Advertisements. *Food and Drug Administration*. Federal Register. 21 C.F.R. §1141. Docket No. FDA-2010-N-0568. http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM339834.pdf.

[116] Song, AV, Brown P, Glantz SA. When health policy and empirical evidence collide: The case of cigarette package warning labels and economic consumer surplus. *American Journal of Public Health*. 12 Dec. 2013. http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2013.301737.

[117] Gruber J. Government policy towards smoking: A view from economics. *Yale Journal of Health Policy, Law, and Ethics*. 2003, 3(1), Art. 7.

consequences of tobacco use and are more likely to underestimate the power of addiction than adults.[118] We strongly emphasize that there should be absolutely no consumer surplus attributable to tobacco product use before the age of 18, especially when it has been shown that 50% of high school smokers have tried quitting but three quarters of this population have continued to smoke into adulthood even with the intention of quitting.[119] One-third of these children and adolescents that develop a long-term addiction to tobacco products will die prematurely from smoking.[120] Further, we find it unacceptable that the FDA so severely underestimates the savings generated though improving the health of the nation's youth through inadequate and inaccurate cost-benefit modeling, and we emphasize that regulating all tobacco products to prevent their use by children will generate significant economic savings in the preservation of the public health.

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[118] Ibid.

[119] Schmidt L. The path to smoking addiction starts at very young ages. Campaign for Tobacco-Free Kids. 27 Mar. 2014. http://www.tobaccofreekids.org/research/factsheets/pdf/0127.pdf.

[120] Ibid.

E-Cigarettes and Liquid Nicotine

Local poison centers report an uptick in liquid nicotine exposures.

Twitter (https://twitter.com/AAPCC) Facebook (https://www.facebook.com/aapcc) RSS (/alerts/rss/)

2,689 Exposures

Jan. 1, 2015, to October 31, 2015

Related Topics

Poison Control in Action › (/prevention/adult-education/)

For More Information

1-800-222-1222
For Media: 703-894-1865

Poison centers are reporting a recent uptick in calls about exposures to e-cigarette devices and liquid nicotine.

Slightly more than half of these reported exposures have occurred in young children under the age of 6. However, this is consistent with National Poison Data System exposures to all substances combined. Some children and toddlers who come in contact with e-cigarette devices or liquid nicotine have become very ill; some even requiring ER visits with nausea and vomiting being the most significant symptoms. Adults should use care to protect their skin when handling the products, and they should be out of sight and out of the reach of children. Additionally, those using these products should dispose of them properly to prevent exposure to pets and children from the residue or liquid left in the container.

The American Association of Poison Control Centers recommends the following steps:

- Protect your skin when handling the products.
- Always keep e-cigarettes and liquid nicotine locked up and out of the reach of children.
- Follow the specific disposal instructions on the label.
- If you think someone has been exposed to an e-cigarette or liquid nicotine, call your local poison center at 1-800-222-1222 immediately.

Click here for the most recent detailed data. (https://aapcc.s3.amazonaws.com/files/library/E-cig__Nicotine_Web_Data_through_10.2015.pdf) (https://aapcc.s3.amazonaws.com/files/library/E-cig__Nicotine_Web_Data_through_9.2015_IAlV9Wr.pdf)

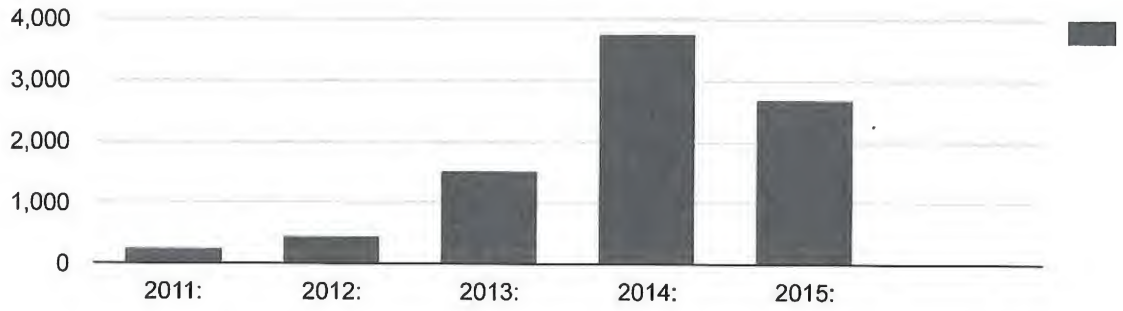
Click here for AAPCC's tobacco & nicotine prevention resource page (http://www.aapcc.org/prevention/tobacco-liquid-nicotine/).

In 2015, through October 31, AAPCC has received 2,689 e-cigarette devices and liquid nicotine reported exposures.

PLEASE NOTE: All NPDS data reported by the American Association of Poison Control Centers for 2014 and 2015 is considered preliminary because it is possible that a poison center may update a case anytime during the year if new information is obtained.

The term "exposure" means someone has had contact with the substance in some way; for example, ingested, inhaled, absorbed by the skin or eyes, etc. Not all exposures are poisonings or overdoses.

E-cigarette Device and Liquid Nicotine Reported Exposures to Poison Centers



Related Press Releases

- American Association of Poison Control Centers Releases Annual Poison Exposure Report › (/press/38/)
- American Association of Poison Control Centers Urges Government Liquid Nicotine Regulation in Wake of Child Death › (/press/37/)
- New E-Cigarette Poisoning Data Reinforce Need for Immediate Government Action to Protect Children › (/press/36/)

- AAPCC Joins 30-member Sign-on Letter Supporting the Child Nicotine Poison Prevention Act of 2014 › (/press/39/)
- AAPCC Issues Statement on the Introduction of the Child Nicotine Poison Prevention Act of 2014 › (/press/30/)

Find Your Local Poison Center

Poison centers offer free, private, confidential medical advice 24 hours a day, 7 days a week. You can reach your local poison center by calling 1-800-222-1222.

Alabama

- Alabama (.)
- Alaska (.)
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